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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,723	10/11/2005	Veronique Coxam	P70904US0	6839

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,723	COXAM ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *3,6,15,17,20 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-14,16,18,19,21-23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/10 has been entered.

Status of Claims

2. Claims 1-26 are pending in this application.

3. Claims 3, 15, 17, and 24 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/8/08.

4. Claims 6 and 20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/8/08.

5. Claims 1, 2, 4, 5, 7-14, 16, 18, 19, 21-23, 25, and 26 are examined.

Response to Arguments

6. Applicant's arguments, see pages 10-13, filed 3/1/10, with respect to the rejection(s) of claim(s) 1, 16, 18, 19, and 21-23 under Hamdi in view of Katori, particularly in view of arguments directed to the Katori reference, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hamdi alone (see paragraph 8, below).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4, 5, 7-14, 16, 18, 19, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamdi et al (US 2003/0004117).

The claimed invention is drawn to a method for inhibiting bone resorption in humans or animals comprising the administration to a subject in need thereof a composition comprising oleuropein as active compound (see claim 1). Applicants have elected osteoporosis as the disease to be treated (see claim 7).

Hamdi et al teach methods for inhibiting angiogenesis comprising administering oleuropein and/or the products of its hydrolysis in therapeutically effective amounts (abstract). Since oleuropein is present in therapeutically effective amounts, it reads on

"active compound." The methods and compositions are particularly effective in inhibiting the vascularization of endothelial cells, and may be utilized to treat a wide variety of cancers, ocular diseases, and inflammatory conditions (abstract). The populations to which the compositions of Hamdi are administered are the same as those of the claimed invention, since persons being treated for cancers, ocular diseases, and inflammatory conditions would also seek to prevent bone loss which occurs with aging, and/or seek to prevent a disorder associated with unbalanced bone formation-bone resorption ratio, and/or might suffer from a condition such as type I or type II osteoporosis or secondary osteoporosis. It is further noted that Hamdi exemplifies a sufficient amount of oleuropein as 0.025 g in a mouse model (see Example 3). Assuming an average weight of 0.02 kg for a lab mouse and 67.5 kg for an average human, this equates to a sufficient amount of oleuropein for a human being 84.3 g, which is within Applicant's range (see claims 14 and 23). Therefore, since the same composition (i.e., a composition comprising oleuropein as active compound) is administered to the same population(s) in the same amount, the same effect(s) would necessarily take place, i.e., stimulation of bone formation and/or inhibition of bone resorption. Therefore, the invention of Hamdi anticipates the claimed invention.

Regarding claims 4, 5, 7, 18, 19, and 21, it is noted that the populations to which the compositions of Hamdi are administered are the same as those of the claimed invention, since persons being treated for cancers, ocular diseases, and inflammatory conditions would also seek to prevent bone loss which occurs with aging, and/or seek to prevent a disorder associated with unbalanced bone formation-bone resorption ratio,

and/or might suffer from a condition such as type I or type II osteoporosis or secondary osteoporosis.

Regarding claims 8 and 9, Hamdi et al teach the compositions may be formulated orally in solid, semi-solid, or liquid form, including powders, slurries, and solutions (see paragraph 74); said forms reasonably read on "a food composition or beverage" in wet or dry form.

Regarding claims 10-13, Hamdi et al teach that the extract may be from olive leaf (i.e., *olea europaea*) (e.g., see paragraph 54).

Regarding claims 14 and 23, Hamdi exemplifies a sufficient amount of oleuropein as 0.025 g in a mouse model (see Example 3). Assuming an average weight of 0.02 kg for a lab mouse and 67.5 kg for an average human, this equates to a sufficient amount for a human being 84.3 g, which is within Applicant's range.

Regarding claim 16, Hamdi et al teach that a pharmaceutical composition of oleuropein may be administered (paragraph 15).

Regarding claim 22, Hamdi et al teach that the compositions may be in a suitable form for oral, parenteral, intraperitoneal, or intradermal administration (paragraph 74).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. The rejection of claims 1, 2, 4, 5, 7-14, 25, and 26 under 35 U.S.C. 103(a) as being unpatentable over Lockwood (US Patent 7,445,807), as evidenced by Nachman (US Patent 5,714,150) has been modified as follows:

11. Claims 1, 2, 4, 5, 7-14, 16, 18, 19, 21-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockwood (US Patent 7,445,807) in view of Nachman (US Patent 5,714,150).

The claimed invention is drawn to a method for inhibiting bone resorption in humans or animals comprising the administration to a subject in need thereof a composition comprising oleuropein as active compound (see claim 1). Applicants have elected osteoporosis as the disease to be treated (see claim 7).

Lockwood teaches agglomerated granular protein-rich nutritional supplements formulated to enhance the nutritional intake of various types of persons of disparate ages, genders, and levels of physical activity, comprising edible nutritional food proteins; edible carbohydrates; edible fats; edible dietary vitamins and minerals; edible amino acids; and **edible plant extracts** (col. 8, lines 28-38) which may include olive leaf extract (col. 9, lines 28-37). Olive leaf extract is known to inherently contain oleuropein; as evidence, Nachman teaches a method of producing olive leaf extract known as oleuropein with valuable medicinal properties, including antiviral activity (see abstract and column 1), and therefore reasonably reads on “active compound”. Therefore, one

skilled in the art of edible plant extracts would envisage oleuropein from the disclosure of "olive leaf extract" in Lockwood, and thus the composition of Lockwood reads on “a composition comprising oleuropein as active compound” as taught in claim 1.

While Lockwood teaches a composition comprising edible plant extracts which may be olive leaf extract (which inherently contains oleuropein), Lockwood does not specifically exemplify a composition comprising olive leaf extract sufficient to anticipate the claimed invention. Therefore, the rejection is made under obviousness.

Nachman teaches a method of producing olive leaf extract known as oleuropein with valuable medicinal properties, including antiviral properties (see abstract and column 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select olive leaf extract as the edible plant extract in the composition of Lockwood, since olive leaf extract provides the benefits of valuable medicinal properties, including antiviral properties, as taught by Nachman (abstract and column 1). Therefore, one skilled in the art would be motivated to select olive leaf extract from the list of edible plant extracts taught by Lockwood for inclusion in its composition, in order to improve the overall health of those taking the composition, including persons of disparate ages, genders, and levels of physical activity.

Additionally, while Lockwood does not specifically teach that the supplement comprising olive leaf extract stimulates bone formation and/or inhibits bone resorption, the populations to which the compositions of Lockwood are administered are the same as those of the claimed invention, since all persons of disparate genders, ages, and

levels of physical activity would seek to prevent bone loss which occurs with aging, and/or seek to prevent a disorder associated with unbalanced bone formation-bone resorption ratio, and/or might suffer from a condition such as type I or type II osteoporosis or secondary osteoporosis. It is further noted that the amounts of edible plant extracts taught by Lockwood (i.e., 50 mg; see col. 14, line 32) fall within the range taught by the claimed invention (see claims 14 and 23). Therefore, since the same composition (i.e., a composition comprising oleuropein as active compound) is administered to the same population(s) in the same amount, the same effect(s) would necessarily take place, i.e, stimulation of bone formation and/or inhibition of bone resorption.

Regarding claims 2 and 22, Lockwood teaches that the supplement is in oral unit dosage form (abstract).

Regarding claims 4, 5, 7, 18, 19, and 21, Lockwood teaches that the supplements may be used for postmenopausal women which are particularly susceptible to osteoporosis (col. 1, lines 35-38); said women would naturally seek to prevent bone disorders, including bone loss which occurs with aging and disorders associated with unbalanced bone formation-bone resorption ratio. Said women also might suffer from type I or type II osteoporosis or secondary osteoporosis.

Regarding claims 8 and 9, Lockwood teaches that the supplement may be in the form of a rapidly dissolvable wafer or dissolved in a liquid (column 19); said forms reasonably read on "a food composition or beverage" in wet or dry form.

Regarding claims 10-13, Lockwood teaches that the extract may be from olive leaf (i.e., *olea europaea*).

Regarding claims 14 and 23, Lockwood teaches that the supplements for women may comprise 50 mg of edible plant extracts (col. 14, line 32). While Lockwood does not explicitly state that the supplements are administered daily, Lockwood does teach that certain components are formulated according to the Recommended Daily Allowance (for example, see col. 9, lines 5-10), and therefore one skilled in the art would reasonably expect that the supplements are administered daily.

Regarding claim 16, Lockwood teaches that its compositions may comprise olive leaf extract, which is known to have valuable medicinal properties as taught by Nachman, and therefore the composition of the combined references reasonably reads on a pharmaceutical composition.

Regarding claims 25 and 26, Lockwood teaches that the supplement may be in the form of a rapidly dissolvable wafer, including a combination of carbohydrate and non-caloric sugar substitute (col. 19, lines 21-26). Said form reasonably reads on "confectionary product" and "cookie".

Response to Arguments

12. Applicant's arguments filed 3/1/10 have been fully considered but they are not persuasive.

Applicants argue that nothing in Lockwood teaches or suggests a method of stimulating bone formation and/or inhibiting bone resorption in humans or animals comprising the administration of a composition comprising oleuropein as active

compound, and that the Examiner has inadvertently engaged in hindsight analysis. Applicants further argue that a person of skill in the art would never, based on the teachings of Lockwood and Nachman, arrive at a method of stimulating bone formation and/or inhibiting bone resorption in humans or animals comprising the administration to a subject in need thereof of a composition comprising oleuropein as active compound. Applicants also argue that nothing in Lockwood nor Nachman teaches or suggest that olive leaf extracts are helpful for treating osteoporosis.

This argument is not persuasive. As noted above, the populations to which the compositions of Lockwood are administered are the same as those of the claimed invention, since all persons of disparate genders, ages, and levels of physical activity would also seek to prevent bone loss which occurs with aging, and/or seek to prevent a disorder associated with unbalanced bone formation-bone resorption ratio, and/or might suffer from a condition such as type I or type II osteoporosis or secondary osteoporosis. It is further noted that the amounts of edible plant extracts taught by Lockwood (i.e., 50 mg; see col. 14, line 32) fall within the range taught by the claimed invention (see claims 14 and 23). Therefore, since the same composition (i.e., a composition comprising oleuropein as active compound) is administered to the same population(s) in the same amount, the same effect(s) would necessarily take place, i.e, stimulation of bone formation and/or inhibition of bone resorption. The claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
Primary Examiner, Technology Center 1600